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PATENT
Attorney Docket No.: 018623-013910US

Assistant Commissioner for Patents
Washington, D.C. 20231

On 7/31/01

TOWNSEND and TOWNSEND and CREW LLP

By: *Neil Frederick*

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

ALESSANDRO SETTE et al.

Application No.: 09/350,401

Filed: July 8, 1999

For: INDUCING CELLULAR IMMUNE
RESPONSES TO HEPATITIS B VIRUS
USING PEPTIDE AND NUCLEIC ACID
COMPOSITIONS

Examiner: R. Schwadron

Art Unit: 1644

INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR §1.97 and
§1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

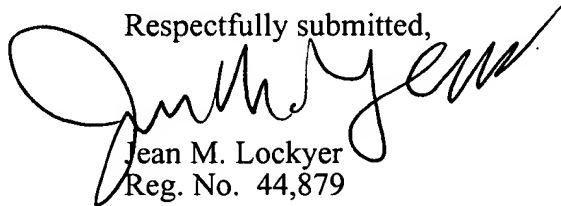
The references cited on attached form PTO-SB/08A and PTO-SB/08B are being called to the attention of the Examiner. Copies of the references are enclosed; however copies of the U.S. Patents are not enclosed as they were originally filed with the corresponding parent application, USSN 09/239,043. Also enclosed is a copy of the International Search Report corresponding to a related PCT application. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the

references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, since it is being submitted prior to the issuance of the first Office Action on the merits. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Jean M. Lockyer
Reg. No. 44,879

TOWNSEND and TOWNSEND and CREW LLP
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known

Application Number 09/350,401
Filing Date July 8, 1999
First Named Inventor
Group Art Unit 1644
Examiner Name R. Schwadron
Attorney Docket Number 018623-013910US

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U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	AA	4,428,941		Galibert <i>et al.</i>	31 Jan. 1984	
	AB	4,599,230		Milich and Chisari	8 July 1986	
	AC	4,599,231		Milich and Chisari	8 July 1986	
	AD	4,818,527		Thornton <i>et al.</i>	4 Apr. 1989	
	AE	4,882,145		Thornton <i>et al.</i>	21 Nov. 198	
	AF	5,017,558		Vyas	21 May 1991	
	AG	5,019,386		Machida and Nakamura	28 May 1991	
	AH	5,039,522		Neurath	13 Aug. 1991	
	AI	5,143,726		Thornton <i>et al.</i>	1 Sept. 1992	
	AJ	6,037,135		Kubo <i>et al.</i>	14 Mar. 2000	

FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	AK	PCT	WO 93/03753					<input type="checkbox"/>
	AL	PCT	WO 93/03764					<input type="checkbox"/>
	AM	PCT	WO 94/03205					<input type="checkbox"/>
	AN	PCT	WO 94/19011					<input type="checkbox"/>
	AO	PCT	WO 94/20127					<input type="checkbox"/>
	AP	PCT	WO 95/03777					<input type="checkbox"/>

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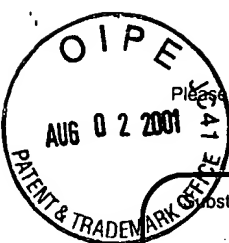
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Sheet 2 of 5

Complete if Known

Application Number	09/350,401
Filing Date	July 8, 1999
First Named Inventor	
Group Art Unit	1644
Examiner Name	R. Schwadron
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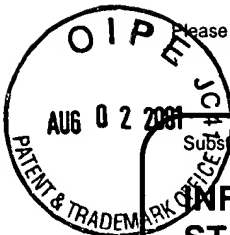
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Sheet 3 of 5

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	AU	Alexander <i>et al.</i> , "Derivation of HLA-A11/K ^b Transgenic Mice" <u>The Journal of Immunology</u> (1997) 159: 4753-4761	<input type="checkbox"/>
	AV	Alexander, <i>et al.</i> "The Optimization of Helper T Lymphocyte (HTL) Function in Vaccine Development" <u>Immunological Research</u> (1998) 18 (2) 79-92.	<input type="checkbox"/>
	AW	Ando <i>et al.</i> , "Mechanisms of Class I Restricted Immunopathology. A Transgenic Mouse Model of Fulminant Hepatitis" <u>J. Exp. Med.</u> (1993) 178: 1541-1554	<input type="checkbox"/>
	AX	Barnaba <i>et al.</i> , "Selective Killing of Hepatitis B Envelope Antigen-specific B cells by Class I-restricted, Exogenous Antigen-specific T Lymphocytes" <u>Nature</u> (1990) 345 258-260	<input type="checkbox"/>
	AY	Bertoletti <i>et al.</i> , "Definition of a Minimal Optimal Cytotoxic T-Cell Epitope Within the Hepatitis B Virus Nucleocapsid Protein" <u>Journal of Virology</u> (1993) 67(4): 2376-2380	<input type="checkbox"/>
	AZ	Bertoletti <i>et al.</i> , "Natural Variants of Cytotoxic Epitopes are T-cell Receptor Antagonists for Antiviral Cytotoxic T Cells" <u>Nature</u> (1994) 369: 407-410	<input type="checkbox"/>
	AAA	Bertoletti <i>et al.</i> , "HLA Class I-restricted Human Cytotoxic T Cells Recognize Endogenously Synthesized Hepatitis B Virus Nucleocapsid Antigen" <u>Proc. Natl. Acad. Sci. USA</u> (1991) 88: 10445-10449	<input type="checkbox"/>
	AAB	Bertoni <i>et al.</i> , "Human Histocompatibility Leukocyte Antigen-binding Supermotifs Predict Broadly Cross-reactive Cytotoxic T Lymphocyte Responses in Patients with Acute Hepatitis" <u>J.Clin. Invest.</u> (1997) 100(3): 503-513	<input type="checkbox"/>
	AAC	Borras-Cuesta <i>et al.</i> , "Engineering of Immunogenic Peptides by Co-linear Synthesis of Determinants Recognized by B and T Cells" <u>Eur. J. Immunol.</u> (1987) 17: 1213-1215	<input type="checkbox"/>
	AAD	Bhatnagar <i>et al.</i> , "Immune Response to Synthetic Peptide Analogues of Hepatitis B Surface Antigen Specific for the a Determinant" <u>Proc. Natl. Acad. Sci. USA</u> (1982) 79: 4400-4404	<input type="checkbox"/>
	AAE	Celis <i>et al.</i> , "Recognition of Hepatitis B Surface Antigen by Human T Lymphocytes" <u>The Journal of Immunology</u> (1988) 140: 1808-1815	<input type="checkbox"/>
	AAF	Chisari, "Hepatitis B Virus Immunopathogenesis" <u>Annu. Rev. Immunol.</u> (1995) 13: 29-60	<input type="checkbox"/>
	AAG	del Guercio <i>et al.</i> , Binding of a Peptide Antigen to Multiple HLA Alleles Allows Definition of an A2-Like Supertype" <u>The Journal of Immunology</u> (1995) 154: 685-693	<input type="checkbox"/>

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Sheet 4 of 5

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Application Number 09/350,401
Filing Date July 8, 1999
First Named Inventor
Group Art Unit 1644
Examiner Name R. Schwadron
Attorney Docket Number 018623-013910US

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Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AAH	Deres <i>et al.</i> , "In Vivo Priming of Virus-specific Cytotoxic T Lymphocytes with Synthetic Lipopeptide Vaccine" <u>Nature</u> (1989) 342: 561-564	<input type="checkbox"/>
	AAI	Fayolle <i>et al.</i> , "In Vivo Induction of Cytotoxic T Cell Response by a Free Synthetic Peptide Requires CD4 ⁺ T Cell Help" <u>The Journal of Immunology</u> (1991) 147 4069-4073	<input type="checkbox"/>
	AAJ	Ferrari <i>et al.</i> , "Identification of Immunodominant T Cell Epitopes of the Hepatitis B Virus Nucleocapsid Antigen" <u>J. Clin. Invest.</u> (1991) 88: 214-222	<input type="checkbox"/>
	AAK	Fujii, <i>et al.</i> , "Synthesis of Peptide Fragments of Hepatitis B Virus Surface Antigen (HBsAg) and Their Immunogenicity" <u>Peptide Chemistry</u> (1983), E.Munekata(Ed.) 215-220	<input type="checkbox"/>
	AAL	Hayashi <i>et al.</i> , "Studies on Peptides, CLXVI. Solid-Phase Syntheses and Immunological Properties of Fragment Peptides Related to Human Hepatitis B Virus Surface Antigen (HBsAg) and Its Pre-S2 Gene" <u>Chem. Pharm. Bull.</u> (1988) 36(12): 4993-4999	<input type="checkbox"/>
	AAM	Hopp, "Immunogenicity of a Synthetic HBsAg Peptide Enhancement by Conjugation to a Fatty Acid Carrier" <u>Molecular Immunology</u> (1984) 21(1): 13-16	<input type="checkbox"/>
	AAN	Ishioka <i>et al.</i> , "Class I MHC-restricted, Peptide-specific Cytotoxic T Lymphocytes Generated by Peptide Priming In Vivo" <u>Vaccines 90</u> (1990) Cold Springs Harbor Laboratory Press pp. 7-11	<input type="checkbox"/>
	AAO	Kondo <i>et al.</i> , "Prominent Roles of Secondary Anchor Residues in Peptide Binding to HLA-A24 Human Class I Molecules" <u>The Journal of Immunology</u> (1995) 155: 4307-4312	<input type="checkbox"/>
	AAP	Lerner <i>et al.</i> , "Chemically Synthesized Peptides Predicted From the Nucleotide Sequence of the Hepatitis B Virus Genome Elicit Antibodies Reactive with the Native Envelope Protein of Dane Particles" <u>Proc. Natl. Acad. Sci. USA</u> (1981) 78(6) 3403-34-7	<input type="checkbox"/>
	AAQ	Milich, "Probing T Cell Antigen Recognition: Use of Synthetic Peptides" <u>Peptide Research</u> (1990) 3(2): 85-96	<input type="checkbox"/>
	AAR	Milich <i>et al.</i> , "Immune Response to Hepatitis B Virus Core Antigen (HBcAg): Localization of T Cell Recognition Sites Within HBcAg/HBeAg" <u>The Journal of Immunology</u> (1987) 139(4): 1223-1231	<input type="checkbox"/>
	AAS	Nayersina <i>et al.</i> , "HLA A2 Restricted Cytotoxic T Lymphocyte Responses to Multiple Hepatitis B Surface Antigen Epitopes During Hepatitis B Virus Infection" <u>The Journal of Immunology</u> (1993) 150(10): 4659-4671	<input type="checkbox"/>

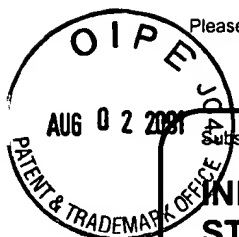
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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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	AAT	Penna <i>et al.</i> , "Hepatitis B Virus (HBV)-Specific Cytotoxic T-Cell (CTL) Response in Humans: Characterization of HLA Class II-Restricted CTLs That Recognize Endogenously Synthesized HBV Envelope Antigens" <u>Journal of Virology</u> (1992) 66(2): 1193-1198	<input type="checkbox"/>
	AAU	Penna <i>et al.</i> , "Cytotoxic T Lymphocytes Recognized an HLA-A2-restricted Epitope Within the Hepatitis B Virus Nucleocapsid Antigen" <u>J. Exp. Med.</u> (1991) 174: 1565-2570	<input type="checkbox"/>
	AAV	Rehermann <i>et al.</i> , "The Cytotoxic T Lymphocyte Response to Multiple Hepatitis B Virus Polymerase Epitopes During and After Acute Viral Hepatitis" <u>The Journal of Experimental Medicine</u> (1995) 181: 1047-1058	<input type="checkbox"/>
	AAW	Ruppert <i>et al.</i> , "Prominent Role of Secondary Anchor Residues in Peptide Binding to HLA-A2.1 Molecules" <u>Cell</u> (1993) 74: 929-937	<input type="checkbox"/>
	AAX	Sallberg <i>et al.</i> , "Human and Murine B-cells Recognize the HBcAg/BETA (or Hbe2) Epitope as a Linear Determinant" <u>Molecular Immunology</u> (1991) 28(7): 719-726	<input type="checkbox"/>
	AAZ	Sette <i>et al.</i> , "The Relationship Between Class I Binding Affinity and Immunogenicity of Potential Cytotoxic T Cell Epitopes" <u>The Journal of Immunology</u> (1994) 153:5586-5592	<input type="checkbox"/>
	AAZ	Sidney <i>et al.</i> , "Specificity and Degeneracy in Peptide Binding to HLA-B7-Like Class I Molecules" <u>The Journal of Immunology</u> (1996) 157: 3480-3490	<input type="checkbox"/>
	AAAA	Toes, <i>et al.</i> "Enhancement of Tumor Outgrowth Through CTL Tolerization After Peptide Vaccination is Avoided by Peptide Presentation on Dendritic Cells" <u>Journal of Immunology</u> (1998) 160:4449-4456	<input type="checkbox"/>
	AAAB	Wakita <i>et al.</i> , "Gamma-Interferon Production in Response to Hepatitis B Core Protein and Its Synthetic Peptides in Patients with Chronic Hepatitis B Virus Infection" <u>Digestion</u> (1990) 47: 149-155	<input type="checkbox"/>

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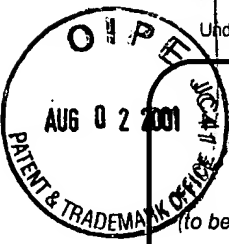
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Application Number 09/350,401

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First Named Inventor

Group Art Unit 1644

Examiner Name R. Schwadron

Attorney Docket Number 018623013910

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